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| 09/069,703      | 04/29/1998  | GILLES H. TAPOLSKY   | VIRO:034            | 3665             |

7590

04/10/2002

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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/10/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/069703

Applicant(s)

TAPOLSKY

Examiner

WEBMAN

Group Art Unit

1617

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- ☒ Responsive to communication(s) filed on 1/8/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-18, 33-34 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-15, 17, 18, 34 is/are rejected.
- ☒ Claim(s) 16, 33 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement

## Application Papers

- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some\* ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 20
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Applicants 131 declaration overcomes Kamiya et al.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-15, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Inaba et al (U.S. patent 4,552,751 equivalent to EPA 0050480).

Inaba et al teach a three-layer composition comprising an outer control release layer comprising polyvinyl pyrrolidone and hydroxy alkyl cellulose (Figure 1 and claim 1A). A drug-storing layer comprising hydroxypropyl cellulose is disclosed (claims 8). Glycerin is specified (claim 1C). Prostaglandin<sup>s</sup>, known for lowering bloods pressure, are disclosed (column 1 line 48).

Vinyl acetate is specified (claim 1B). AS to the claimed adhesive layer, this property must be inherent in the Inaba et al composition because it possesses the same polymer as that claimed as an adhesive, namely, polyvinyl pyrrolidone.

Applicants argue that Inaba et al only teaches 3 layers. However, applicants' "comprising" language encompasses more than two <sup>y</sup> layers.

Similarly, applicants argue that Inaba et al teaches water-insoluble polymers. However, applicants' "comprising" language includes such polymers.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

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was filed, had possession of the claimed invention. Nowhere in the specification do applicants disclose a flavoring agent.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7/16/02  
[Signature]  
Claims 1-~~6~~ 9, 11, ~~12~~ 14, 15, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/05416 ('416).

'416 teaches a composition comprising an adhesive layer and other layers, which are water-soluble and contain an active (Abstract).

Hydroxypropyl cellulose in combination with PVP is disclosed (page 12 line 29 page 13 line 1). Thicknesses are specified (page 13 lines 11-12). Hydroxypropyl cellulose is disclosed in a second layer (page 15 lines 7-16). An overlapping adhesive layer is specified (page 30 lines 16-21). Anesthetics are specified (page 9 line 21).

Claims 1-15, 17, 18, 34 are rejected. Claims 16, 33 are objected to as dependent on rejected claims.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday from 9 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR

March 27, 2002

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500